Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effects of Coenzyme Q10 on the serum concentration of interleukin 6 and interleukin 33 in hemodialysis patients

Protocol summary

Summary

Objectives: The main goal of this study is evaluation of anti-inflammatory effects of coenzyme Q10 (CoQ10) in hemodialysis patients. Design: This study is a randomized single blind (the researchers who measure the serum concentration of interleukins and analyze results have no information about the group assignment of the patients) clinical trial. One hundred thirty hemodialysis patients will be recruited from 2 dialysis centers. Setting and conduct: Patients will be assigned to the intervention or control group using the simple blocked randomization. Duration of the study is 3 months. Participants: Patients undergoing regular hemodialysis for at least 3 months will be entered to the study. Patients with active infection and who are consuming anti-inflammatory drugs or warfarin will be excluded. Intervention: Patients will receive CoQ10 capsules at dose of 100 mg daily in the intervention group. In the control group patients will only receive their routine drugs. Main outcome measures: Primary outcome variables: Serum concentration of interleukin 6 and interleukin 33 Secondary outcome variable: Adverse effects

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015061722637N2**
Registration date: **2017-05-21, 1396/02/31**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-05-21, 1396/02/31

Registrant information

Name

Naemeh Nikvarz

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Kerman University of Medical Sciences

Expected recruitment start date

2017-02-25, 1395/12/07

Expected recruitment end date

2017-08-25, 1396/06/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of Coenzyme Q10 on the serum concentration of interleukin 6 and interleukin 33 in hemodialysis patients

Public title

Evaluation of the effects of Coenzyme Q10 on the serum concentration of interleukin 6 and interleukin 33 in hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients who are undergoing regular hemodialysis for at least 3 months will be entered.

Exclusion criteria: Being in active infection phase, having autoimmune diseases, consuming immunosuppressive medications or warfarin, pregnancy, breast feeding

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **130**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Office of Vice chancellor for research, Ebn-e-sina Street

City

Kerman

Postal code

Approval date

2017-02-18, 1395/11/30

Ethics committee reference number

IR.KMU.REC.1395.862

Health conditions studied

1

Description of health condition studied

End Stage Renal Disease (Hemodialysis)

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5 Chronic uraemia End stage kidney disease: in allograft failure NOS on dialysis without dialysis or transplant

Primary outcomes

1

Description

Serum concentration of interleukin 6

Timepoint

At baseline and at the end of the study

Method of measurement

ELISA kit

2

Description

Serum concentration of interleukin 33

Timepoint

At baseline and at the end of the study

Method of measurement

ELISA kit

Secondary outcomes

1

Description

Adverse effects

Timepoint

During the study

Method of measurement

Patients' report

Intervention groups

1

Description

Intervention 1: CoQ10 100 mg oral capsules, Dosage: 100 mg once daily, Duration: Three months

Category

Treatment - Drugs

2

Description

Intervention 2 (control group): No treatment, Duration: Three months

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Hospital

Full name of responsible person

Naemeh Nikvarz

Street address

Shafa Hospital, Kowsar Boulevard

City

Kerman

2

Recruitment center
Name of recruitment center
Javad-ol Aemeh Dialysis Center
Full name of responsible person
Naemeh Nikvarz
Street address
25th Alley, North Aboozar Street
City
Kerman

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kerman University of Medical Sciences
Full name of responsible person
Abbas Pardakhti
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Office of Vice chancellor for research, Ebn-e-sina Street
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Kerman
Grant name
Grant code / Reference number
95000191
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Kerman University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty